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Virgil Lee Beaston
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Jane Shershenovich*
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Andrea J. Kamage
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LuAnne M. DeSantis
John J. Figueroa
Ann E. Summerfield
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Jessica L. Parezo

Timothy A. Doyle*
Gaby L. Longworth*
Nicole D. Dretar*
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Registered Patent Agents*
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*Admitted only in Maryland
*Admitted only in Virginia
*Practice Limited to
Federal Agencies

May 25, 2004

WRITER'S DIRECT NUMBER:
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INTERNET ADDRESS:
BHAANES@SKGF.COM

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Mail Stop Issue Fee

Re: U.S. Utility Patent Application
Application No. 09/557,907; Filed: April 21, 2000
For: **Methods for Treating Cancer Using Cytokine-Expressing
Polynucleotides (as amended)**
Inventors: HORTON *et al.*
Our Ref: 1530.0060004/EKS/EJH/PAC

Sir:

Pursuant to a telephone conversation between Examiner Wilson and the undersigned representative on May 17, 2004, Applicants transmit the following documents herewith for appropriate action:

1. A copy of the SKGF Cover Letter as originally filed on April 15, 2004;
2. A copy of the Fourth Supplemental Information Disclosure Statement as originally filed on April 15, 2004;
3. A copy of the six pages of Form PTO-1449 listing 17 documents as originally filed on April 15, 2004;
4. Copies of the 17 documents as listed on Form PTO-1449 (AL4-AM4, AT42, AR43-AT43, AR44-AT44, AR45-AT45, AR46-AT46, AR47 and AS47) as originally filed on April 15, 2004;
5. A copy of the postcard date stamped by the USPTO on April 15, 2004; and

Commissioner for Patents
May 25, 2004
Page 2

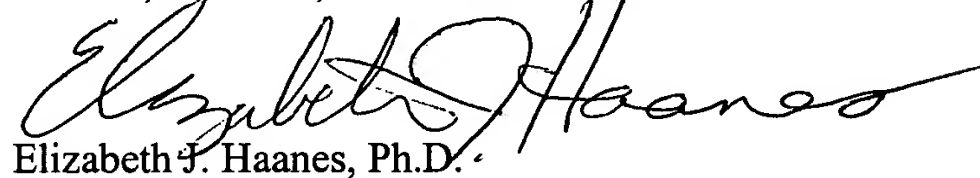
6. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Elizabeth J. Haanes", is written over the printed name.

Elizabeth J. Haanes, Ph.D.
Attorney for Applicants
Registration No. 42,613

EJH/PAC/dbj

Enclosures

268289_1.DOC

**Sterne Kessler
Goldstein Fox**



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Jorge A. Goldstein
David K.S. Cornwell
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April 15, 2004

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FILE COPY

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1632

Re: U.S. Utility Patent Application
Application No. 09/557,907; Filed: April 21, 2000
For: **Methods for Treating Cancer Using Cytokine-Expressing
Polynucleotides (as amended)**
Inventors: HORTON *et al.*
Our Ref: 1530.0060004/EKS/EJH/PAC

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Fourth Supplemental Information Disclosure Statement;
2. Six pages of Form PTO-1449 listing 17 documents;
3. Copies of the 17 documents as listed on Form PTO-1449 (AL4-AM4, AT42, AR43-AT43, AR44-AT44, AR45-AT45, AR46-AT46, AR47 and AS47); and
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Commissioner for Patents
April 15, 2004
Page 2

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Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Elizabeth J. Haanes, Ph.D.

Attorney for Applicants

Registration No. 42,613

EJH/PAC/dbj

Enclosures

252530_1.DOC



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Horton *et al.*

Appl. No.: 09/557,907

Filed: April 21, 2000

For: **Methods for Treating Cancer
Using Cytokine-Expressing
Polynucleotides**

Confirmation No.: 9397

Art Unit: 1632

Examiner: Wilson, Michael C.

Atty. Docket: 1530.0060004/EKS/EJH/PAC

Fourth Supplemental Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each document is also provided.

The numbering on this Fourth Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Third Supplemental Information Disclosure Statement filed February 27, 2004, and Applicants' Information Disclosure Statement filed July 20, 2000, in connection with the above-captioned application.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

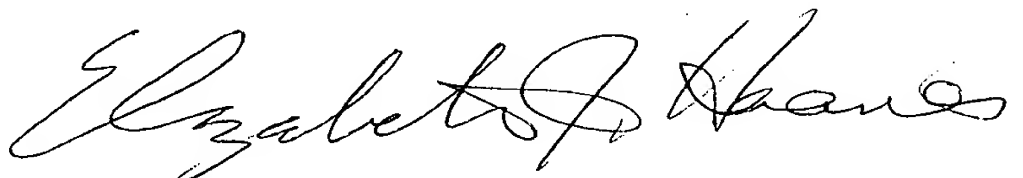
This Fourth Supplemental Information Disclosure Statement is being filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

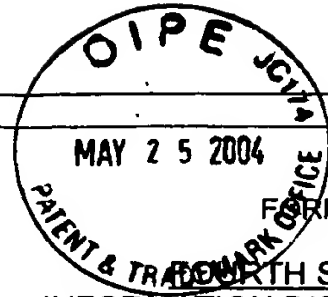
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Elizabeth J. Haanes, Ph.D.
Attorney for Applicants
Registration No. 42,613

Date: April 15, 2004

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600



MAY 25 2004

FORM PTO-1449

FOURTH SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
1530.0060004/EKS/EJH/PACAPPLICATION NO.
09/557,907FIRST NAMED INVENTOR
Horton *et al.*FILING DATE
April 21, 2000ART UNIT
1632

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL4	WO 98/08947 A1	03/05/1998	WIPO			Yes No
	AM4	WO 99/26663 A2	06/03/1999	WIPO			Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR		
	AS		
	AT	42	Acsadi, G., <i>et al.</i> , "Direct Gene Transfer and Expression into Rat Heart in Vivo," <i>New Biol.</i> 3:71-81, W.B. Saunders (1991)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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Page 2 of 6

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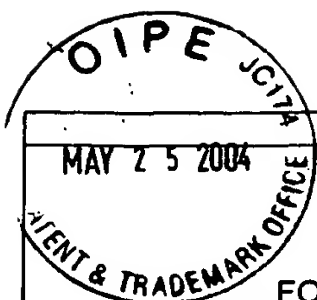
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>43</u>	Brunda, M.J., <i>et al.</i> , "Antitumor and Antimetastatic Activity of Interleukin 12 against Murine Tumors," <i>J. Exp. Med.</i> 178:1223-1230, The Rockefeller University Press (1993)
	AS	<u>43</u>	Chen, Y., <i>et al.</i> , "DNA Vaccines Encoding Full-Length or Truncated Neu Induce Protective Immunity against Neu-Expressing Mammary Tumors," <i>Canc. Res.</i> 58:1965-1971, American Association for Cancer Research (May 1998)
	AT	<u>43</u>	Desnick, R.J. and Schuchman, E.H., "Gene therapy for genetic diseases," <i>Acta Paediatr. Jpn.</i> 40:191-203, Blackwell Scientific (June 1998)

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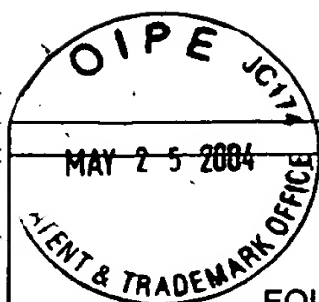
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>44</u>	Hersh, E.M., and Stopeck, A.T., "Advances in the Biological Therapy and Gene Therapy of Malignant Disease," <i>Clin. Canc. Res.</i> 3:2623-2629, American Association for Cancer Research (December 1997)
	AS	<u>44</u>	Irvine, K.R., <i>et al.</i> , "Cytokine Enhancement of DNA Immunization Leads to Effective Treatment of Established Pulmonary Metastases," <i>J. Immunol.</i> 156:238-245, The American Association of Immunologists (January 1996)
	AT	<u>44</u>	Jiao, S., <i>et al.</i> , "Direct Gene Transfer into Nonhuman Primate Myofibers <i>In Vivo</i> ," <i>Hum. Gene Ther.</i> 3:21-33, Mary Ann Liebert, Inc. (1992)

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Page 4 of 6

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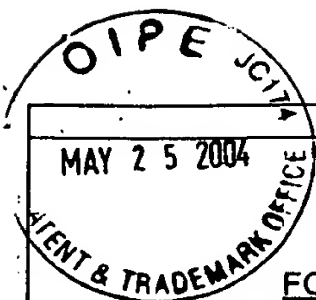
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>45</u>	Mandl, C.W., <i>et al.</i> , "In vitro-synthesized infectious RNA as an attenuated live vaccine in a flavivirus model," <i>Nat. Med.</i> 4:1438-1440, Nature America Inc. (December 1998)
	AS	<u>45</u>	Marshall, E., "Cancer Trial of Interleukin-12 Halted," <i>Science</i> 268:1555, American Association for the Advancement of Science (1995)
	AT	<u>45</u>	Moelling, K., "Naked DNA - the poor man's gene therapy?" <i>Gene Ther.</i> 5:573-574, Stockton Press (May 1998)

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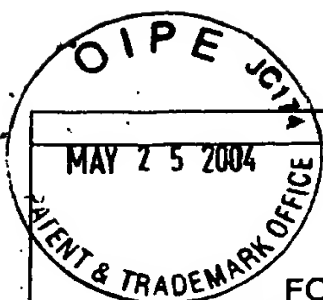
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>46</u>	Rakhmievich, A.L., <i>et al.</i> , "Gene gun-mediated skin transfection with interleukin 12 gene results in regression of established primary and metastatic murine tumors," <i>Proc. Natl. Acad. Sci. USA</i> 93:6291-6296, National Academy of Sciences (June 1996)
	AS	<u>46</u>	Sun, W.H., <i>et al.</i> , " <i>In vivo</i> cytokine gene transfer by gene gun reduces tumor growth in mice," <i>Proc. Natl. Acad. Sci. USA</i> 92:2889-2893, National Academy of Sciences (1995)
	AT	<u>46</u>	Tan, J., <i>et al.</i> , "Injection of Complementary DNA Encoding Interleukin-12 Inhibits Tumor Establishment at a Distant Site in a Murine Renal Carcinoma Model," <i>Canc. Res.</i> 56:3399-3403, American Association for Cancer Research (August 1996)

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	AR	<u>47</u>	Wigginton, J.M., <i>et al.</i> , "Administration of Interleukin 12 With Pulse Interleukin 2 and the Rapid and Complete Eradication of Murine Renal Carcinoma," <i>J. Natl. Canc. Inst.</i> 88:38-43, Oxford University Press (January 1996)
	AS	<u>47</u>	Xiang, Z., and Ertl, H.C.J., "Manipulation of the Immune Response to a Plasmid-Encoded Viral Antigen by Coinoculation with Plasmids Expressing Cytokines," <i>Immunity</i> 2:129-135, Cell Press (1995)
	AT		

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Applicants: HORTON *et al.*

Due Date: NONE

Art Unit: 1632

Confirmation No. 9397

Examiner: Wilson, Michael C.

Docket: 1530.0060004

Atty: EKS/EJH/PAC

Application No.: 09/557,907

Filed: April 21, 2000

For: **Methods for Treating Cancer Using
Cytokine-Expressing Polynucleotides (as
amended)**

When receipt stamp is placed hereon, the USPTO acknowledges receipt of the following documents:

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